NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

ON-SITE ASSESSMENT

CHAPTER 3

DRAFT STANDARDS
Revision 1

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On-Site Assessment Committee

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NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

CHAPTER #3 - ON-SITE ASSESSMENT

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3.0 On-site Assessment

3.1 Introduction

The on-site assessment is an integral and requisite part of a lab accreditation program and will be one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team will collect and evaluate information and make observations which will be used to judge ~~evaluate~~ the laboratory's conformance with established accreditation criteria.

It is essential that the on-site assessment conducted by any accrediting authority in the United States wishing to be recognized by the National Environmental Laboratory Accreditation Program be conducted in a uniform, consistent manner. Reasons for fostering this consistency include a need to improve the base quality of data coming from the laboratories; to allow more confident comparision of results generated by different laboratories; ~~throughout the nation~~ to facilitate reciprocity among States; and for the laboratory community to accept the accreditation process.

This section ~~contains~~ describes the essential elements that are to be included in any acceptable on-site assessment, ~~proposals and recommendations for conducting on-site assessments~~, and the qualifications and requirements for assessors.

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) should be described to the appropriate laboratory official, and reported to the appropriate state or federal agency. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with all applicable health and safety regulations.

3.2 On-Site Assessment Personnel

3.2.1 Training

The National Environmental Laboratory Accreditation Conference (NELAC) will specify the minimum level of education and training for assessors, including refresher/update training. The NELAC will also develop criteria for training requirements. The assessor training program ~~course~~ will be developed and implemented by either accrediting authorities, ~~EPA~~, ~~state~~ accrediting bodies ~~organizations~~, or other entities ~~NIST, or a non-Federal entity with~~ subject to EPA oversight ~~by EPA~~. ~~A state may develop and implement it's own~~ All assessor training programs, ~~subject to EPA oversight, if the state program can~~ must meet the NELAC standards.

Until such time as the NELAC has developed and published training requirements for laboratory assessors, each accrediting authority shall approve the training and experience requirements for each of its assessors.

When the NELAC has completed the development and promulgation of assessor training program standards, and the NELAP has been established by the USEPA, accrediting authorities, accrediting bodies, or other entities may petition the NELAP for approval of a formal training program that meets the NELAC standards.

3.2.2 Qualifications

A laboratory assessor may work for a Federal, State, or a third party accrediting body. An assessor, ~~including each member of an inspection team,~~ must be an experienced professional and hold at least a B.S. degree, or equivalent education and experience, ~~in the specific discipline being evaluated~~ in laboratory operation or assessment and related fields.

Each assessor must also have satisfactorily completed a NELAC-approved assessor ~~laboratory accreditation~~ training program ~~course and a health and safety training course~~ and take periodic update/refresher training, as specified by NELAC. Each new candidate assessor must undergo training with a qualified assessor ~~on-the-job training~~ during ~~one~~ four or more ~~inspections~~ actual assessments until judged proficient by the accrediting authority.

3.2.3 Additional qualifications

In addition, the assessors must:

a) Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;

b) Have a thorough knowledge of the relevant assessment methods and assessment documents;

c) Be thoroughly familiar with the various forms of records described in 3.5.3 Records Review;

d) Be thoroughly cognizant of contemporary data reporting, analysis, and reduction techniques and procedures;

e)~~c~~ Be technically conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling procedures;

f)~~d~~ Be able to communicate effectively, both orally and in writing; and,

g)~~e~~ Be free of any commercial or other interest that might cause the assessor to act in other than an impartial or non-discriminatory manner.

3.2.4 Assessor Certification

Before an assessor can conduct on-site ~~inspections~~ assessments, the individual must be certified to do so, in writing, by either the NELAP or primary State in which the individual will assess laboratories. For each laboratory ~~inspection~~ assessment performed by a state-designated third party assessor (i.e. non-EPA, non-State), the assessor must sign a statement before the ~~inspection~~ assessment, certifying that no conflict of interest exists, and provide whatever supporting information is required by the state accrediting agency or NELAP guidelines. Failure to provide this information will make the proposed assessor ineligible to participate in the assessment program.

3.3 Frequency of On-Site Assessments

3.3.1 Frequency

Accrediting authorities ~~accreditors~~ must ~~should~~ require ~~perform~~ an ~~a routine~~ on-site assessment of each facility that is accredited at least every two years ~~annually~~. Assessments may be more frequent at laboratories where a specific problem exists or is suspected, including situations where complaints about laboratory quality have been received, ~~questions of fraud~~, or ~~recurring~~ failure on performance evaluation samples has occurred.

3.3.2 Follow-up evaluations

In addition to routine evaluations, assessors may need to conduct ~~one-time~~ follow-up evaluations at laboratories where a significant deficiency was identified by the previous evaluation. These evaluations may be, but are not necessarily, limited to determining whether a laboratory has corrected its deficiency(ies), or determining the merit of a formal appeal from the laboratory. When deficiencies are of such severity as to possibly warrant downgrading of accreditation status, any follow-up assessment that is planned or conducted must be completed and reported within forty-five days ~~may result in downgrading of accreditation status, follow-up evaluations should occur as soon as possible but no later than 60 days after the original evaluation~~.

Nothing in this section should be construed as requiring an accrediting authority to reassess a facility prior to taking a regulatory or administrative action affecting the status of the facility's accreditation. Nothing in this section should be construed as limiting in any way the accrediting authorities ability to revoke or otherwise limit a laboratory's accreditation upon the identification of such deficiencies as to warrant such action.

3.3.3 Changes in laboratory capabilities

The accrediting authority may also deem necessary ~~a~~ an ~~limited one-time~~ assessment ~~evaluation~~ when a major change occurs at a laboratory in personnel, equipment, or a laboratory location that might impair analytical/biological capability and quality. A major change in personnel is defined as the loss or replacement

of the laboratory management staff, or loss of a trained and experienced individual who performs a particular test for which accreditation has been granted.

3.3.4 Announced and unannounced visits

The accrediting authority is not required to provide advance notice of an assessment. ~~However, the policy is to provide such notification, based on the circumstances of the particular assessment and laboratory. Since these highly technical assessments may involve sensitive information and because there is a need to ensure that appropriate personnel and records are available for assessment, the testing laboratory usually is notified in advance of a planned assessment.~~ The accrediting authority, at its discretion, may conduct unannounced or announced on-site assessments ~~evaluations for cause, (e.g., questions of fraud, tips, complaints, or problems with performance evaluation samples) or as part of a routine practice~~.

3.4 Pre-Assessment Procedures

3.4.1 Introduction

A good assessment begins with planning, which should commence well before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. These activities include obtaining records before the assessment, conducting the assessment, writing reports and following up.

Pre-assessment activities include: deciding the scope of the assessment ~~(Section 3.4.2)~~; assessment planning ~~(Section 3.4.3)~~; reviewing NELAP/State information ~~(Section 3.4.4)~~; providing advance notification of the assessment to the laboratory ~~(Section 3.4.5)~~; coordinating the assessment team ~~(Section 3.4.6)~~; and gathering assessment documents ~~and equipment (Section 3.4.7)~~. Section 3.4.6 ~~8~~ discusses Confidential Business Information (CBI) issues.

3.4.2 Scope of the assessment

The first step in the assessment planning process is deciding what type of assessment will be conducted. The assessment may be

a general one to assess the capability of the lab to perform environmental testing or specific examination of a certain area of testing. The assessments ~~usually~~ must include both a laboratory evaluation and a records review. The assessment for a field of testing must cover all of the tests for which the lab seeks accreditation, or has already been accredited.

3.4.2.1 Laboratory evaluations

~~A laboratory assessment obtains a "snapshot in time" at a testing laboratory by evaluating what activities are being conducted when the assessment takes place.~~ A general laboratory assessment should review the overall ability of the lab to conduct environmental testing. The examination of the processes and procedures of the lab should give a general sense of its past and present capabilities to perform accurate work without major deficiencies. During a laboratory evaluation, the assessment team may identify a number of samples or a recently completed or on-going project and evaluate to what extent the tests are being conducted according to NELAC standards ~~NELAP or client requirements~~.

3.4.2.2 Records review

The purpose of a records review is to ~~learn~~ ascertain whether ~~if~~ the testing laboratory has maintained necessary documentation of data and other information ~~necessary~~ to support reports previously issued. During a records review, team members will conduct an overall audit of data, and will compare data with submitted reports to determine whether the data were generated or collected following the proper NELAC procedures ~~in the NELAP/State, EPA, or client requirements~~.

3.4.3 Assessment planning

Planning includes conducting a thorough review, prior to the assessment, of NELAP and/or State records pertaining to the laboratory to be inspected. This will save time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit. Planning also promotes a better relationship with the laboratory community because the lead assessor will be better able to answer questions concerning the application of NELAC ~~NELAP/State requirements~~ standards to a particular laboratory.

It also enhances the laboratory's confidence in the lead assessor and aids in establishing good relationships with laboratory representatives.

Another important benefit of planning is to enhance the lead assessor's ability to identify and document potential problems and plan to collect necessary information to assist the accrediting authority in their subsequent decisions concerning the laboratory. Planning an assessment will result in an efficient and productive assessment overall.

3.4.4 Reviewing NELAP/State information

~~The lead assessor's responsibilities start with receipt of the Assessment Assignment~~. Prior to initiating an on-site assessment, the assessment team shall make a specific judgment as to which laboratory records they wish to review prior to the actual site visit. ~~For a records review, copies of all appropriate documents related to the laboratory will be forwarded by the accrediting authority to the lead assessor or directly to a team member, if appropriate, ideally at least six weeks prior to the start of the assessment. The lead assessor should request any other information that will be useful in preparing for the assessment. Such information may include:~~ These records, from the files of the accrediting authority or the national laboratory accreditation data base maintained by the NELAP shall include:

a) Copies of previous assessment reports and PE sample results, including the results of assessments done by other accrediting authorities that are contained in the national laboratory accreditation data base operated by NELAP;

b) General laboratory information such as laboratory submitted self-assessment forms, SOPs and Quality Assurance plan;

c) ~~Correspondence with laboratory personnel;~~ Official laboratory communications;

d) Records of official communications ~~discussion~~ with appropriate NELAP/State staff;

e) Available documents from recipients of reports from the

laboratory; ~~and,~~

f) Relevant program documents such as NELAP/State guidelines or SOPs;

g) The laboratory's application for accreditation;

h) The existing program regulations and special requirements that apply to the areas for which accreditation is sought; and

i) The methodologies that are most recently approved for the tests for which the laboratory has requested accreditation.

Note: Sections 3.4.5 and 3.4.6, as published in the December 2, 1994, Federal Register, will be moved to the assessor's training manual for consideration.

~~**3.4.5 Providing advance notification**~~

~~No fewer than two weeks prior to an announced assessment, the accrediting body will contact the responsible management official at the laboratory to schedule the assessment. The initial telephone notification will be confirmed by a notification letter. A copy of the notification letter also will be given to the lead assessor. An assessment assignment that gives the name and telephone number of the laboratory contact person and of each assessment team member, as well as other available information necessary to the planning and conduct of the assessment will also be provided to the lead assessor.~~

~~Once the laboratory has been notified by the accrediting authority that an assessment will be conducted, the primary responsibility for the conduct of the assessment passes to the lead assessor. Any further communications with the laboratory personnel should be made by the lead assessor. The lead assessor should keep his/her supervisory personnel informed of the status of the assessment, and should consult with them on any substantive problems that may arise or changes that may be required.~~

~~There are several items to be addressed in the advanced notification. The lead assessor should make note of when and to~~

whom advance notification was provided. Written advance notification should do the following:

a) Introduce the lead assessor and team members to the laboratory;

b) Schedule the assessment, including establishing time of arrival;

c) Obtain verbal agreement for entry;

d) Confirm the appropriate address for the assessment, including identifying the location of necessary records, as specified in the assessment plan;

e) Ensure that laboratory personnel are available to accompany assessors during the assessment;

f) Encourage the laboratory to transfer all records to the assessment site before the assessment;

g) Obtain directions to the laboratory; and,

h) Allow discussion of problems, concerns, or questions about the assessment or any other issues.

Especially when the laboratory has not previously been assessed by the accrediting authority, the lead assessor should be certain that laboratory personnel are aware of what an assessment involves, what data and records should be made available and what personnel should be present. If the laboratory representative does not cooperate, the lead assessor's supervisor and the accrediting authority management should be consulted for instructions on how to proceed.

3.4.6 Assessment Team Coordination

When the identity of the assessment team is known, the lead assessor should contact each person and begin planning the conduct of the assessment. As early as possible the lead assessor should:

a) Coordinate travel plans, including the hotel and transportation arrangements;

b) Notify each team member of the dates of the assessment and pre-assessment team meeting;

c) Ensure that each team member has been briefed on specific procedures for the assessment;

d) Define the time allotted for the assessment. The lead assessor should be careful not to underestimate the time needed to conduct the assessment; and,

e) Confirm for those individuals who will be conducting the records review, their familiarity with the records to be reviewed. Each member of the assessment team should be aware of their responsibilities during the assessment.

The lead assessor should also arrange to provide copies of applicable NELAP/State standard operating procedures (SOPs) to team members who do not already possess these documents. In addition, the lead assessor may need to assure that the assessment team is aware of proper procedures for receipt and handling of confidential business information (CBI). The lead assessor should determine the level of experience of each team member in conducting laboratory evaluations or records reviews under NELAP/State requirements. The lead assessor may need to guide less experienced team members, both prior to and during the assessment as well as with report preparation. The lead assessor should assemble the team just prior to the assessment to attend to last minute details.

3.4.7 Gathering assessment documents and equipment

Besides preparing the assessment plan and reviewing accrediting body records and laboratory submissions prior to conducting the assessment, the lead assessor should gather and prepare the necessary documents and equipment to be used during the assessment. No single list of documents and equipment can be appropriate for all assessments. The lead assessor's experience in the field and information obtained during pre-assessment planning should assist in preparing lists tailored to specific assessment sites and needs. Specific needs will be determined by the requirements of the assessment, the availability of equipment, conditions at the laboratory, NELAP/State policies, and whether advance notification of an assessment is given.

3.4.5 ~~7.1~~ Assessment documents

Documents necessary for the assessment and which may need to be provided to the laboratory management or staff should be ~~prepared~~ assembled before the assessment, whenever possible. The lead assessor should obtain copies of the required assessment forms, including the NELAC approved checklist. ~~Several spare copies of each form should always be carried.~~ Other types of documents that may be required include ~~Assessments may require~~:

- ~~Notice of Assessment;~~
- Assessment Confidentiality Notice;
- Conflict of Interest Form;
- Assessor Credentials;
- Assessment Assignment;
- Assessment Notification letter;
- Attendance sheet, opening and closing conference; and,
- Assessment Appraisal Form

In addition, the lead assessor should be able to provide information on how to obtain copies of ~~certain to take the following~~ documents and materials ~~on an~~ associated with an assessment.

~~a) Copies of NELAP/State requirements. Lead assessors should have copies of the applicable NELAP/State requirements available upon request. Having such data available can help improve the relationship between NELAP/State and the laboratory community, which can foster better laboratory compliance;~~

~~b) NELAP/State checklists for evaluations;~~

~~c) NELAP/State outreach materials. Lead assessors should provide current, relevant educational, and/or guidance information to laboratory officials upon request or as deemed appropriate by~~

~~the lead assessor; and,~~

~~d) Administrative information. Travel authorizations and telephone numbers of travel and procurement personnel who may need to be contacted should be taken by the lead assessor when on travel.~~

~~3.3.7.2 Assessment equipment~~

~~The types of equipment that a lead assessor takes to an assessment site will vary from assessment to assessment, depending upon the nature and extent of the assessment and the type of testing laboratory to be inspected. Therefore, prior to each assessment, the lead assessor should check the equipment to make sure that it is in good working condition. Since each assessment is unique, no single list of equipment or forms can be devised that will fit every assessment situation.~~

3.4.6~~8~~ Confidential Business Information considerations

During on-site assessments, it is likely that the accrediting agency staff will come into possession of some confidential business information, such as names and addresses of clients, rates charged different clients, trade secrets, including some formulations of reagents etc. that may be part of the assessment information but which must be protected from unauthorized release. For this data to be adequately protected, certain actions are required immediately prior to or at the onset of the on-site assessment.

NELAP/State SOPs protect Confidential Business Information (CBI) from disclosure. CBI includes trade secrets (including process, formulation, or production data) and certain financial information, the uncontrolled disclosure of which could cause damage to a laboratory's competitive position. In general, disclosure of CBI is prohibited, except in certain limited situations.

~~The lead assessor should keep in mind that information obtained from a laboratory during an assessment can, for the most part, be disclosed in response to a request from the public, or other requesting party, under Federal or State Freedom of Information requirements. However, if the data has been properly claimed as CBI, it may not generally be disclosed under these requirements.~~

A lead assessor must present notice to laboratory representatives of their right to claim data at the laboratory as CBI and such claims are frequently made. Because the lead assessor is very likely to require access to CBI before (i.e., while preparing for an assessment), during, and after an assessment, the lead assessor must be knowledgeable of NELAP/State procedures governing access to, handling of, and disclosure of CBI. The lead assessor and others who may use the information must have CBI access authorization, since only authorized individuals may have access to CBI. A CBI-cleared lead assessor may obtain access to CBI documents from the accrediting authority by requesting access to the information from the appropriate official.

Whether or not it is anticipated that CBI documents will be collected during an assessment, the lead assessor must provide a NELAP/State assessment confidentiality notice to the responsible laboratory official at the beginning of the assessment. This notice informs laboratory officials of their right to claim part of the assessment data as CBI. The lead assessor should be familiar with the procedures for asserting a CBI claim, and the criteria that the claimed information must meet.

The lead assessor must take custody of all CBI documents before leaving the laboratory, and must maintain them in custody, using all proper procedures and safeguards, until they can be received by the accrediting authority.

3.5 Assessment Schedule/Format

3.5.1 Length of evaluation

The length of an on-site assessment will depend upon a number of factors, such as the number of tests for which a laboratory desires accreditation ~~evaluated~~, the number of assessors available, the size of the laboratory, the number of problems encountered during the assessment, and the cooperativeness of the laboratory staff. The accrediting body should assign an adequate number of assessors to complete the evaluation within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, but in all cases must assure that the laboratories' operations meet all of the NELAC standards, except as noted in the final report ~~assuring that the assessment covers all aspects of the laboratory operation~~.

3.5.2 Opening conference

Arrival at the facility should normally occur during established ~~normal~~ working hours. The ~~facility representative~~ responsible laboratory official should be located as soon as the assessment team arrives on the premises.

A laboratory's refusal to admit the assessment team for an evaluation ~~may~~ can result in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation ~~on the part of~~ by the laboratory, unless there are extenuating circumstances that are accepted and documented by the accreditation ~~body~~ authority. The team leader ~~should~~ must notify the accrediting ~~body~~ authority as soon as possible after refusal of entry.

Topics that must be addressed during the opening conference are:

a) the purpose of the assessment;

b) the identification of the assessment team;

c) the specific tests that will be examined;

d) the specific records and operating procedures to be examined during the assessment, and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documentation;

e) the roles and responsibilities of key managers and staff in the laboratory;

f) the procedures related to Confidential Business Information;

g) any special safety procedures that the laboratory may think necessary for the protection of the assessment team while in certain parts of the facility (under no circumstance is an assessment team required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility);

h) the specific standards and criteria that will be used by the assessors in judging the adequacy of the laboratory operation;

i) confirmation of the tentative time for the exit conference; and

j) completion of the assessment appraisal form by the responsible laboratory official (to be submitted to NELAP and the accrediting authority).

~~When the appropriate official has been located, the team leader should introduce the team and should present credentials. Many companies require that the assessment team sign a visitor's sheet that contains the name, time, reason for visit, organization, etc., which should be signed. However, any request for any assessment team member to sign a "visitor's release" or "waiver" that would relieve the company of responsibility for injury or that would limit the rights of the accrediting body to use the data obtained should not be signed. If such a waiver or release is presented, the team leader should politely explain that they cannot sign and request a blank sign-in sheet. The assessment team leader should "brief" the appropriate responsible official(s) of the facility to introduce team members, explain areas to be evaluated and verify application information.~~

~~The assessment team leader should request relevant documents for review that were not part of the application materials, such as Standard Operating Procedures, Chain-of-Custody forms, report~~

~~forms, etc.~~

~~The assessment appraisal form should be presented to the appropriate laboratory official with a request that the form be completed and returned to the accrediting authority after the assessment. This form will allow feedback from the laboratory on the manner in which the assessment was conducted.~~

3.5.3 Records review

The records requested during the opening conference will be reviewed by assessment team members for accuracy, completeness and proper methodology for each ~~area~~ test and analyte to be evaluated.

A minimum record set that must be examined during a NELAP accreditation on-site assessment includes;

a) application for accreditation from the laboratory;

b) previous assessment results and reports including PE analysis results;

c) laboratory management structure and chains of responsibility (e.g. organizational charts);

d) qualifications statements of all key staff involved in the analysis or reporting of results for which accreditation has been requested and a matching of the staff qualifications with the statements submitted with the applications;

e) quality assurance plans for the entire laboratory;

f) quality assurance plans for each analytical procedure for which the laboratory seeks accreditation;

g) standard operating procedures and methodologies for each analytical test for which accreditation is sought;

h) maintenance and calibration records of specific pieces of laboratory equipment separate and apart from that encompassed in analyte specific records;

i) procedures for the make-up and calibration of stock solutions and standard reagents;

j) records asssociated with the acquisition and use of calibration and standard reference materials;

k) records associated with the use of matrix spiked duplicates on a procedure by procedure basis as well as the use and documentation for fortified blanks;

l) the specific records associated with the initial method validation study in the laboratory which must be examined in detail with the routine long term calibration data;

m) records associated with the methods used to estimate precision and accuracy in general and on a test by test basis;

n) sample receipt and handling documentation;

o) PE sample receipt and handling procedures;

p) information on the PE providers, including the documentation provided by the PE provider indicating it's accreditation by NELAP; and

q) records of any internal audits conducted by the laboratory itself.

Trade secrets and confidential business information are protected from public disclosure. The type of information that may be considered confidential business information is defined in Title 40, Code of Federal Regulation, Part 2. All financial and trade information should be kept confidential, if so requested by the laboratory. All other information for all aspects of application, assessment and accreditation of laboratories is considered public information. If the laboratory requests that information other than noted above is confidential, the information should be treated as confidential until a ruling can be made by the accreditation body.

The team leader must mark all confidential information received

and handle it as required by appropriate laws and regulations.

3.5.4 Staff interviews

~~The assessment team will evaluate a test by having the individual that normally conducts the specific procedure walk through the procedure, including a step-by-step description of exactly what is done and what equipment and supplies are employed.~~

~~The assessor will note and record the procedure on the standardized checklists for that particular test and application. Any deficiencies shall also be noted and discussed with the individual.~~

~~During the evaluation, sufficient information may become available to indicate that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information should be carefully documented, since it may be used in a legal action. When the possibility of additional legal investigation exists, the assessor should not discuss the specific violation with the individual or any representative of the laboratory.~~

As an element of the assessment process, the assessment team may evaluate an analysis regimen by having the analyst that normally conducts the procedure give a step-by-step description of exactly what is done and what equipment and supplies are needed. During this assessment or appraisal, the assessor will note and record the procedure on the standardized checklists for that particular test and application. Any deficiencies shall also be noted and discussed with the analyst. The deficiencies will also be discussed in the closing conference.

The assessment team members shall have the authority to conduct interviews with any/all staff and, if necessary, conduct private interviews. Calculations, data transfers, calibration procedures, quality control/assurance practices, and adherence to SOPs shall be assessed for each test with the appropriate analysts(s).

During the evaluation, sufficient information may become available to indicate that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information should be carefully

documented since ~~it may be used in a legal action~~ further action may be necessary. ~~Where the possibility of additional legal investigation exists, the assessor should not discuss the legal implications of the suspected violation with the individual or any laboratory representative.~~ In the event that evidence of said unethical and/or potentially illegal activities have or may have occurred, the assessment team should present such information to the accrediting authority for appropriate actions. These issues, at the discretion of the assessment team, may or may not be subjects or issues of the closing conference. However, the assessor should continue to gather the information necessary to complete the accreditation assessment.

3.5.5 Closing conference

The assessment team should meet with representatives following the evaluation of the laboratory for an informal debriefing and discussion of findings with the possible exception of any issues of unethical and/or potentially illegal activity which may be the subject of further action. It should be noted that the assessment team in no way limits its ability to identify additional problem areas in the final report should that become necessary.

In the event the laboratory disagrees with the findings of the assessor(s), and the team leader adheres to the original findings, the ~~area(s) protested~~ deficiencies with which the laboratory takes exception shall be documented by the team leader and included in the report to the accreditation ~~body~~ authority for consideration. The accrediting authority will make the final determination.

The assessment team should ~~provide~~ inform the ~~accreditation body with~~ laboratory representative that an assessment report encompassing all relevant information concerning the ability of the applicant laboratory to comply with the accreditation requirements is forthcoming. ~~If data is available from performance evaluation testing, this should be included in the final report.~~

3.5.6 Follow-up procedures

The accrediting authority will issue the assessment report to the applicant laboratory ~~that outlines~~ outlining any area of

~~deficiencies~~ deficiency. The applicant laboratory ~~should~~ must then submit a plan of corrective action and supporting documentation that address all deficiencies noted in the report, ~~if necessary, and provide any missing documentation required~~ not later than thirty days from when the report is received. ~~within 45 days from the date of report receipt~~.

After reviewing the assessors reports and any corrective action noted by the laboratory, ~~documentation and corrective actions,~~ the accrediting authority will make the decision to pass, fail or provide interim accreditation for a laboratory.

If the deficiencies listed are substantial or numerous, an additional on-site assessment ~~(possibly unannounced)~~ may be conducted before a final decision for accreditation can be made.

3.6 Criteria For Assessment

Note: Section 5, Quality Systems Contains Details of Criteria for Assessment

3.6.1 Assessor's manual

The NELAC will develop a manual(s) for on-site assessors to assure that on-site assessments are performed in a uniform, consistent manner. The manual(s) will be provided when assessors take the NELAC required training (section 3.2.1) and will serve as guidance for on-site assessment personnel.

The manual(s) provided to on-site assessors should include instructions for evaluating the following items:

a) Size, appearance, adequacy of the laboratory facility;

b) Organization and management of the laboratory;

c) Qualifications and experience of laboratory personnel;

d) Receipt, tracking and handling of samples;

e) Quantity, condition, performance of laboratory instrumentation and equipment;

f) Preparation and traceability of calibration standards;

g) ~~Analytical and biological methodology (including the laboratory's standard operating procedures as well as confirmation of individuals' adherence to SOPs, and the individual's proficiency with the methodology)~~ Test methods (Including the adequacy of the laboratory's standard operating procedures as well as confirmation of individual's adherence to SOPs, and the individual's proficiency with the described task);

h) Data reduction procedures, including an examination of raw data and confirmation that final reported results can be traced to the raw data/original observations;

i) Quality assurance/quality control procedures, including adherence to the laboratory's quality assurance plan and adequacy of the plan;

j) General health and safety procedures as they relate to good laboratory practices;

k) Laboratory waste disposal procedures;

l) Environmental and toxicological test methods and SOPs; and,

m) Care, use, and maintenance of test organisms.

3.6.2 Assessor's role

When performing an on-site laboratory ~~evaluation~~ assessment, the assessor must appraise each of the areas listed in section 3.6.1, and perform a thorough evaluation of the records for each of the tests for which accreditation has been requested.

The on-site assessor should use a variety of tools in the evaluation process. The experience of the assessor, his/her observations, interviews with laboratory staff, and examination of SOPs, raw data, and the laboratory's documentation ~~will~~ all play an important role in the assessment. ~~The role of the on-site assessor is a critical one in the entire laboratory accreditation process~~. The accreditation of a particular laboratory will depend to a large extent on the ~~assessor's~~ assessment team's findings and recommendations. While much of the on-site assessment will depend upon the assessor's judgement,

the recommendation not to accredit a laboratory, or to change a laboratory's accreditation status, must be based on factual information, not on opinions or suppositions. Therefore it is crucial that the on-site assessor have a clear understanding of the laboratory's procedures and policies, and that the assessor document any deficiencies in the report of the on-site assessment.

The assessment team must use specific documentation in its reporting of deficiencies. ~~Also t~~The assessor should discuss any deficiencies with the laboratory's management at the exit conference ~~in order to~~ and allow them to provide additional information which might affect the assessor's findings and recommendations.

3.6.3 Checklists

Standardized checklists approved by NELAC must be used for the on-site assessment.

The use of checklists does not ~~discourage~~ replace the need for ~~additional~~ observations and staff interviews, but is ~~merely~~ another tool ~~in the assessor's inventory~~ which assists in conducting a thorough and efficient evaluation. ~~Using a~~ A checklist ~~as a~~ is not a substitute for assessor training and experience ~~must not occur~~.

Note: It is anticipated that standardized checklists will be developed or adopted by NELAC's On-Site Assessment Committee for the assessor's review of ~~analytical and biological methodology~~ test methods.

3.6.4 Evaluation criteria

The following considerations should be taken into account by on-site assessors when evaluating the areas listed in section 3.6.1:

3.6.4.1 Facility assessment

The assessor(s) should tour the laboratory facility with the laboratory management representative. Usually the tour will occur during the initial phase of the on-site visit, perhaps after the opening conference. During the tour, the assessor should visually inspect the facility with respect to general

housekeeping, cleanliness, lighting, bench space and continuous temperature monitoring (if required). The assessor should note whether the appropriate laboratory services (e.g., vacuum system, compressed air, gases, etc.) are available. It may be necessary to have the laboratory representative demonstrate that certain pieces of equipment are working properly, for example, a fume hood may be turned on to assure that it does indeed exhaust air from the laboratory. This type of demonstration is not intended to certify that the hood meets design specifications or safety requirements, but merely that it is operational.

During the tour, the assessor(s) should determine if sample storage areas are sufficient and whether there are problems with laboratory operations which would affect data quality. For example, an extraction operation located in the same room where volatile organic analyses are performed could contribute contamination to the volatile organic analyses.

Any problems or deficiencies with the laboratory facility should be brought to the attention of the laboratory management at the time of the tour and reinforced at the closing conference. If discrepancies are noted between statements made by the laboratory representative and visual observations, it may be necessary to interview other laboratory personnel to obtain an explanation of the situation. ~~As with all areas of the on-site assessment, the experience and training of the on-site assessor are critical to the success of the facilities evaluation.~~

3.6.4.2 Organization assessment

The assessor should review laboratory QA plans, SOPs, organizational charts and/or other documentation to determine the laboratory's operational structure. ~~If a documented organizational plan exists,~~ The assessor ~~should~~ must ascertain during subsequent interviews with laboratory personnel if the laboratory operation follows the documented plan. The assessor should interview laboratory management to determine the roles of management and how laboratory policy is created. The absence of a documented organizational structure, clearly defined functional responsibilities, and lines of communication, ~~should be~~ is ~~considered~~ a deficiency.

3.6.4.3 Personnel assessment

The assessor should review the laboratory's written qualification requirements for ~~each~~ key positions, and the qualifications of those persons currently holding the positions. Key personnel, e.g., laboratory management staff, quality assurance coordinator, section managers, chief analysts, etc., should be interviewed to verify their qualifications for their positions. These interviews may be conducted concurrently with interviews on ~~analytical and biological procedures~~ test methods, quality control requirements, etc., ~~in order~~ to expedite the process. The assessor should be cautious when making judgements on personnel qualifications, and must be aware that experience may be an acceptable substitute for formal education. When in doubt concerning personnel qualifications, the assessor should conduct an in-depth interview with the individual to determine his/her expertise in a given area.

~~**Note: Section 5, Quality Systems, contains details on personnel qualifications.**~~

3.6.4.4 Sample handling assessment

The assessor should review the laboratory's SOP for sample receipt to assure that all appropriate elements (e.g., proper sample containers, preservatives, chain of custody, sample storage, sample rejection policy, etc.) are included. Any omissions should be brought to the attention of the laboratory management and appropriate laboratory staff person. Absence of a written sample receipt SOP ~~should be considered a serious~~ is a deficiency. The assessor should inspect the sample storage areas to insure that the facilities are adequate and secured. Cold storage facilities should be checked for maintenance of proper temperatures, proper monitoring devices (thermometers, etc.) and appropriate documentation. Sample receipt personnel should be interviewed to determine their adherence to the SOP. Sample receipt documentation and chain-of-custody records should be reviewed to determine if documentation is adequate. Failure to follow SOPs may be ~~considered~~ a ~~serious~~ deficiency, depending on the degree of deviation. Failure to keep sample receipt and chain-of-custody documentation ~~should be considered~~ is a ~~serious~~ deficiency.

3.6.4.5 Equipment assessment

The assessor should determine if the laboratory has all equipment and instrumentation required by the referenced methods which are necessary to perform the analyses ~~for which certification is requested~~. This determination should be performed by visual inspection of the laboratory. The assessor should determine if the equipment is in reasonable working condition. An actual demonstration of equipment performance is not necessary in all circumstances, but should be required if the assessor has doubts about the condition of certain pieces of equipment. The absence of a required piece of equipment or instrument for a particular test ~~should be considered a serious~~ is a deficiency. The assessor should determine if the laboratory has written records of equipment repairs, maintenance, testing and calibration.

3.6.4.6 Calibration standards assessment

The assessor shall ascertain whether the laboratory has the necessary stock calibration standards and should spot check calibration standards to see if they are within expiration dates. The assessor should determine if stock standards are properly stored, e.g., volatile organic standards are stored in sealed vials in a freezer. The assessor should examine the laboratory's records for stock standards and the preparation of working standards to determine if the records are complete.

3.6.4.7 Methodology assessment

The assessor should determine whether the laboratory has standard operating procedures for all test methods used by the laboratory. The standard operating procedures should be reviewed to determine if they adequately address all aspects of the analytical and biological procedures, e.g., sample preparation, calibration standard preparation, instrument calibration, etc. The analysts should be interviewed to verify that they have access to and are following the standard operating procedures for all methods. The lack of analytical and biological standard operating procedures or significant deviations from the standard

operating procedures ~~should be considered as serious~~ are deficiencies.

While the ideal on-site assessment would consist, in part, of observing each individual perform his/her assigned work, time considerations will not permit this approach in a laboratory which conducts a wide variety of analytical or biological procedures. Consequently, the on-site assessor will need to rely more heavily on interviews with laboratory personnel, observations, and review of records to determine proficiency with, and knowledge of, the analytical or biological methodology. The assessor's experience and training will play a key role in this process.

The assessor should be familiar with the performance of a test, so that the appropriate technical questions may be asked of the laboratory's analysts. The assessor should pose questions to the laboratory's staff in such a way as to not lead the individual into the correct response. The individual's responses should be ~~cross-checked with~~ verified against the laboratory's documentation. During interviews with the individuals, it may be unclear as to how the analytical and biological procedures are being performed. If this occurs, then the assessor should ask the individual to demonstrate the procedure.

3.6.4.8 Data audit

Data audits and records reviews generally involve checking the data that supports reported results. Verification of data essentially involves determining that the supporting data is on file, and further and as importantly, that one data record supports another. The role of the assessor is to look for inconsistencies and discrepancies, especially those that have a tendency to cause final results to vary significantly. Dates and times associated with specific records often prove critical in searching out anomalies in the records of analytical results. In addition to analytical records, assessors are well advised to familiarize themselves with study related correspondence as well.

Among the specific records to be examined are the analyte specific standard operating procedures for the methods being

used. Not only should these SOPs articulate the specific steps that are contained in the approved methodology, they should also note any and all deviations or adjustments that were necessary to make the method work in the facility being inspected.

Of the more important analytical records that must be examined in addition to the SOPs mentioned above are those related to documentation of the methods actual performance in the laboratory.

These include documentation of:

instrument calibration, instrument stability, precision and accuracy, detection/sensitivity and external PE evaluation.

Oftentimes the line between what is required by an approved methodology and what changes are allowed without prior approval is very fine. Accordingly, any and all changes must be evaluated by the laboratory for potential impact on analytical results and the impact documented in the method performance validation records.

The categories of records which must be reviewed in the evaluation of the use of a specific methodology, at a minimum, include records of:

a) Instrument performance;

records on the analysis of calibration standards at the concentrations of interest; results obtained from method blanks; records that have demonstrated the drift or stability of the instrument over time; results of method sensitivity determinations; check standard results over time; precision and accuracy determinations on the specific instrument; and of course a basic initial method validation record.

b) Calibration Procedures;

those records that establish the relationship between the measured quantities such as weight,

absorbance, volume of titrant etc, to the concentration of the analyte to be measured using accurate reference materials. Calibration records should be examined at the ranges that bracket or include the concentrations that are to be found in typical samples, and if the method is used for a broad range of concentrations then the calibrations records should cover those ranges.

These records must be both analyte, instrument, and matrix specific, especially for complex wastes. Calibrations of reagent blanks should also be included in the assessors scrutiny. Any reported sample values above or below the documented calibration ranges should be searched out, and the data behind any calibration curves must be examined on matrix by matrix basis.

c) Instrument and Method Stability;

records reporting the results of check sample analysis every ten to twenty samples and at the beginning and end of each analytical run. records that demonstrate that the check samples concentrations were selected to bracket the expected measured concentrations.

Continuing checks of the analytical balance calibrations should also be examined, especially the recording of Class S weight values each time the balance is used.

records related to the calibration of such items as the thermometers, titrimetric equipment, incubator or bath temperatures etc.

d) Maintenance of Laboratory Instruments;

Records associated with the routine and exceptional repair or maintenance of scientific instrumentation, and any ancillary equipment must be examined by the assessor.

e) Method Performance and Method Validations;

The initial method validation in a laboratory must be examined to assure that the validation did in fact involve the analysis of certified reference material prepared first as four replicates in laboratory pure water, and carried through all the steps of the methodology, including any up-front extraction procedures. The specifics of the record that must be examined include name of analyst, complete record of the procedure used, date, tabulations of obtained results versus calculated results, as well as calculated precision and accuracy data. Similar data must be available for the various concentration values that make up the initial calibration curves as well.

The assessor should perform a data audit on an appropriate number of sample sets which contain all the tests for which the laboratory is seeking accreditation. It may be necessary to audit multiple sample sets in order to cover all tests. The assessor should verify that the required sample receipt documentation and chain-of-custody records are on file and that they contain all necessary information. The assessor should obtain final data reports for the sample set being audited. The assessor should verify that the final reports contain the following information:

- Sample receipt date;
- Sample analysis date;
- Sample identification;
- Method used for analysis;
- Quantitation units, e.g., mg/L, mg/Kg, µg/m^3, etc.;
- If sample is a solid, whether results are calculated on a wet weight or dry weight basis, and if a on dry weight basis, the percent moisture or percent solids;
- The sample result (if the result is none detected,

the ~~method detection~~ reporting limit should also be reported); and,

- Method of statistical determination of test result, if applicable.

The assessor should assure that all information needed to verify the final result is on file, including reasons for invalidating testing results if this has occurred. ~~The information may include sample preparation data, instrument output (chromatograms, mass spectra, strip charts), instrument calibration records, and records of dilutions.~~ Once the information is provided by the laboratory ~~located~~, the assessor should recreate the calculation in order to verify the final reported result. The absence of the required information needed to verify the final result ~~should be~~ is ~~considered~~ a ~~serious~~ deficiency.

If the assessor is unable to recreate a calculation, the problem should be discussed with laboratory personnel and other members of the assessment team in an attempt to resolve the issue. If any calculations/final results are determined to be incorrect, the assessor should examine approximately ten percent of the data for the test in question over a selected time period to see if a systematic error has occurred.

In addition to auditing results from routine sample analyses, assessors must also audit results of performance evaluation (PE) samples analyzed by the laboratory for the NELAP. Assessors should verify that the sample(s) were analyzed using the criteria set forth by NELA~~P~~C.

The data generated during the analysis of PE samples should be examined and compared with final results reported to the NELAP. Any differences should be reported to the accrediting authority.

3.6.4.9 QA Plan assessment

The assessor ~~should~~ must examine the laboratory's written QA Plan to determine if it conforms to the Quality Systems requirements in Section 5. The assessor should examine the laboratory's raw data to ascertain if the required QC checks

have been documented. If QC criteria were exceeded, the assessor must determine if corrective action was initiated. Laboratory personnel should be interviewed to determine if they understand and follow the requirements of the QA Plan. Laboratory management should be interviewed to determine their commitment to the QA program.

The absence of a QA Plan, or an incomplete QA Plan, ~~should be considered~~ is a ~~major~~ deficiency. The lack of appropriate corrective action or documentation of corrective action ~~should be~~ is also ~~considered~~ a ~~serious~~ deficiency.

3.6.4.10 General health and safety procedures

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor[1]. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) should be described to the appropriate laboratory official, and reported to the appropriate state or federal agency. **The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with all applicable health and safety regulations.**

3.6.4.11 Laboratory waste disposal assessment

The assessor(s) should ask if adequate facilities are available for the collection, storage and/or treatment (if applicable) of all laboratory wastes. The waste disposal system(s) should be operated in such a manner to protect the air, water, and land by minimizing and controlling all releases from fume hoods and bench operations. Compliance is also required with any wastewater discharge permits and regulations. It is the laboratory's responsibility to comply with all federal, state, and local regulations governing waste management, particularly the hazardous waste regulations. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with all applicable waste disposal regulations.

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[1] Handbook for Analytical Quality Control in Water and Wastewater Laboratories, EPA-600/4-70-019, March 1979.

3.7.0 Documentation Of On-Site Assessment

3.7.1 Checklists

The checklists used by the assessors during the assessment should become a part of the permanent file kept by the NELAP/State on each laboratory.

3.7.2 Report format

Evaluation reports should be generated in a narrative format~~, allowing for differences in style and technique between accrediting authorities~~. Deficiencies must be addressed at a minimum~~, however, documentation of positive aspects should be included~~. Documentation of existing conditions at the laboratory should be included in each report to serve as a baseline for future contacts with the facility.

Evaluation reports will contain:

a) Identification of organization assessed (name and address)

b) Date of the assessment

c) Identification of the assessment team members (name and affiliation, lead assessor identified)

d) Identification of participants in the assessment process

e) Statement of the objective of the assessment

f) Summary

g) Assessment findings and requirements

h) Comments and recommendations

The final report shall be written to contain a description of the adequacy of the laboratory as it relates to the evaluation criteria in Section 3.6.4. The section on Findings and Requirements must be specifically stated so that both the finding (deficiency) is understood and the

specific requirement is outlined. The section on Comments and Recommendations can be used to convey recommendations aimed at helping the lab improve.

3.7.3 Distribution

The accrediting authority should be recognized as having the responsibility for the content of the evaluation reports. The team leader should compile, edit and submit the final report to the accrediting authority. The team leader must assure that the results within the final report conform to established criteria for the evaluated parameters.

3.7.4 Report Deadline

No longer than thirty (30) days ~~should~~ may elapse from the last day of an on-site evaluation until the report is ~~submitted to the~~ completed by the accrediting authority and copies transmitted to the laboratory and the National Accreditation Database ~~for review and final decision~~. An exception to this deadline may be necessary in those circumstances where an investigation or other regulatory action has been initiated.

3.7.5 Release of Report

On-site evaluation reports should be initally released by the accrediting authority only. The reports will be released to the management of the affected laboratory ~~and to those persons nominated by the laboratory to receive a copy of the report~~. The assessment report shall not be released until ~~the assessment and all other appropriate action has been completed~~ findings of the assessment have been finalized, all Confidential Business Information has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory.

In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, financial and/or trade information, or relevant to an ongoing enforcement investigation, will be considered exempt from release to the public.

3.7.6 Report Storage Time

~~At a minimum,~~ Copies of all evaluation reports must be retained

by the evaluators and the accrediting authority for a period of at least five years, or longer if required by specific state or federal regulations.